REMARKS

A. Prior Election/Restriction Requirement

Applicants acknowledge their election of claims 5 and 6, and have withdrawn all other pending claims.

B. Information Disclosure Statement

The Office Action states that references submitted with May 3, 2004 Information Disclosure Statement (IDS) were not available to Examiner. Applicants have resubmitted herewith all references cited in the May 3, 2004 IDS.

C. The claims as filed fulfill the requirements of 35 U.S.C.§112, 1st paragraph

The Office Action rejects Claims 5 & 6 under 35 U.S.C. §112, first paragraph. The Action asserts that while the isolated polypeptide comprising the amino acid sequence set forth in SEQ ID NO:2 satisfies the written description requirement, the specification fails to meet the written description requirement for a genus of MC-4 receptor antagonists because no particular structures associated with a MC-4 receptor antagonist are disclosed.

Applicants respectfully contravene the assertion that the specification does not describe species within the genus of MC-4 receptor antagonists, and distinguish the pending claims from situations where written description for species within a functionally-defined genus was lacking. See *University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916 (Fed. Cir. 2004); *Enzo Biochem. v. GenProbe, Inc.*, 296 F.3d

1316 (Fed. Cir. 2002). The specification conveys to one of skill in the art that applicant was in possession of a broad range of MC-4 receptor antagonists as of the filing date. Figure 5 indicates that αMSH analogue SHU9119 is a potent MC-4 receptor antagonist (page 27, lines 23-4). Similarly, Figures 7 & 9 illustrate agouti-related peptide's MC-4 receptor antagonist activity. In addition, MC-4 receptor agonists were known in the art at the time this application was filed, and the application discloses additional, novel uses for these compounds.

In addition to the identification of a sub-set of specific MC-4 receptor antagonists, the specification also provides a method for identifying additional MC-4 receptor antagonists. For example, Example 3 describes the development of a novel assay for the detection of MC-4 receptor agonists and antagonists. Thus, the specification provides adequate description of MC-4 receptor antagonists. Applicants respectfully request that the rejections under 35 U.S.C. §112, first paragraph be withdrawn.

The Office Action rejects Claims 5 & 6 under 35 U.S.C. §112, first paragraph. The Action asserts that the specification while enabling for a method of *treating* cachexia, the specification does not reasonably provide enablement for *preventing* a pathological feeding behavior/cachexia by administering a receptor antagonist. Applicants direct the Examiner to the following teachings in the specification:

Cachexia is often disease related and occurs in "cancer patients, cystic fibrosis and AIDS sufferers, and in cases of renal failure (page 16, lines 26-28). Thus individuals who suffer from such disorders, for example, are at high-risk for developing cachexia and in turn would benefit from the administration of MC-4 receptor antagonists prior to the development of cachetic symptoms. In addition, page 37 of the specification describes

an *in vivo* experiment to assess the ability of an MC-receptor to "prevent the onset of cachexia and maintain normal feeding and growth." In a tumor model, the administration of MC-4 receptor antagonist prevented tumor-induced decline in food intake (page 37, line 9). Thus, one of skill in the art would conclude the specification enables the prevention of a pathological feeding behavior/cachexia by the administration of receptor antagonist. Withdrawal of this rejection of claims 5 & 6 under 35 U.S.C. §112, first paragraph is requested.

E. <u>The claims are not anticipated by the cited prior art.</u>

The Office Action rejects Claims 5 & 6 under 35 U.S.C. 102(e) as being anticipated by Cone *et al.* The Office Action states that claims 5 & 6 are drawn to method of preventing a "pathological feeding behavior," while the Cone et al. reference teaches the administration of compounds to an animal that has fasted for "at least 12 hours." Applicants respectfully contend that Cone *et al.* reference does not contain each and every claim limitation of the pending claims, and thus does not anticipate the claimed invention. An animal that has fasted for a few hours fails to meet the claim limitation "pathological feeding behavior." The teachings of the Cone reference are not directed towards cachexia, a recognized pathological feeding behavior that results in wasting. Accordingly, Applicants respectfully request withdrawal of these grounds of rejection.

The Office Action rejects Claims 5 & 6 under 35 U.S.C. 102(e) as being anticipated by Dooley *et al.* As the Office Action points out, the Dooley *et al.* reference does not characterize treated HP 228 (analogue of αMSH) treated rats as suffering from cachexia. Dooley does not describe the pathology of its rats as cachetic because the

animals do not suffer from cachexia. The short-term administration of HP 228 is not the equivalent of a "pathological feeding behavior" or "cachexia." Furthermore, it is inaccurate to correlate an acute reduction in weight and loss of appetite to cachexia. Thus, applicants respectfully contend that Dooley *et al.* does not anticipate the pending claims. Accordingly, Applicants respectfully request that this ground of rejection be withdrawn.

The Office Action rejects Claims 5 & 6 under 35 U.S.C. 102(e) as being anticipated by Bednarek *et al.*

Applicants respectfully contend that the Bednarek reference is not enabling for treating cachexia. The reference contains but a passing reference to cachexia as a feeding disorder that might be addressed by the compounds disclosed in the reference. Applicants respectfully contend that to be anticipatory a reference must enable one of skill in the art to practice the claimed invention, and the Bednarek reference fails to enable and thus to anticipate. *Elan Pharmaceuticals Inc. v. Mayo Foundation for Medical Education & Research*, 346 F.3d 1051 (Fed. Cir. 2003); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313 (Fed. Cir. 2003); *Akzo N.V. v. U.S. Int'l. Trade Comm'n.*, 808 F.2d 1471 (Fed Cir. 1998), citing *In re Brown*, 329 F.2d 1006, 1011 (Fed. Cir. 1990). "An anticipating reference must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter *existed* and that its existence was recognized by persons of ordinary skill in the field of the invention." *ATD Corp. v. Lydall, Inc.*, 48 U.S.P.Q.2d 1321, 1328 (Fed. Cir. 1998), citing *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990)

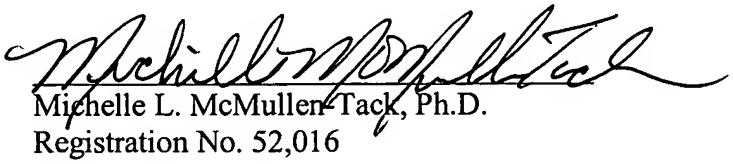
Applicants respectfully contend that the Bednarek reference does not satisfy this criterion. It is in the instant application that for the first time Applicants demonstrate that MC4-R antagonists are effective in treating and preventing cachexia in established animal tumor models. Applicants respectfully contend that the teachings of the Bednarek reference are insufficient to anticipate the pending claims, and request that the Examiner withdraw this ground of rejection.

CONCLUSION

It is believed that all requirements of patentability are fully met, and allowance of the claims is respectfully requested.

If the Examiner believes it to be helpful, he or she is invited to contact the undersigned attorney by telephone at 312-913-3344.

Respectfully submitted,
McDonnell, Boehnen, Hulbert, and Berghoff LLP

By: 
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